

# Bit Market Services

Informazione Regolamentata n. 0472-37-2016	Data/Ora Ricezione 22 Luglio 2016 09:33:28	MTA - Star
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Societa' : BB BIOTECH

Identificativo : 77249

Informazione  
Regolamentata

Nome utilizzatore : BIOTECHNSS01 - Alderuccio

Tipologia : IRAG 02

Data/Ora Ricezione : 22 Luglio 2016 09:33:28

Data/Ora Inizio : 22 Luglio 2016 09:48:29

Diffusione presunta

Oggetto : Interim Report of BB Biotech AG as of June  
30, 2016

*Testo del comunicato*

Vedi allegato.

Media release as of July 22, 2016

Interim Report of BB Biotech AG as of June 30, 2016

## Stabilization of biotech sector in the second quarter of 2016

### BB Biotech returned to profit in Q2 2016

The biotech sector stabilized during the second quarter. BB Biotech's Net Asset Value (NAV) increased by +1.4% in CHF and +2.3% in EUR, resulting in a net profit of CHF 36 mn. Despite the positive trend witnessed during the past few months, BB Biotech's net result for the first half was a negative CHF 1,170 mn due to the loss reported for the first quarter. BB Biotech shares closed the second quarter slightly lower, down -2.7% in CHF and -1.2% in EUR. An increasing disconnect has been observed between the share prices of companies in BB Biotech's portfolio and their positive operational performance. Valuations of biotech blue chips have dropped to levels last seen in 2010/11. Meanwhile company fundamentals remain positive, notwithstanding the increasing attention that drug-pricing practices have received. From an operating standpoint, the companies are performing well and setting new milestones.

The global equity markets showed continued volatility in Q2 2016. The US Federal Reserve Bank's decision to defer again interest rate increases and the UK referendum to leave the European Union were notable. Overall market performance for Q2 2016 was mixed. Positive total returns were recorded for the S&P 500 of 2.5% in USD, European indices such as the DAX showed negative 2.9% performance in EUR, the SMI was positive 4.7% in CHF, and the Nasdaq Biotechnology Index (NBI) more or less stable with negative 1.1% in USD.

The disconnect in value between strong progress reported in biotechnology relative to the equity market valuation continued to widen. Biotechnology stocks have underperformed general equity markets by around 20% since January 2016. The following can be summarized for the biotech sector in 2016:

- Valuations for biotech blue chip companies have fallen to previous lows of 2010/11, trading significantly below large pharmaceutical company multiples and below the average S&P multiple. Many small and mid-sized market cap biotech firms continue to trade at record low pipeline valuations.
- Healthcare reform discussions continue, and the drug industry has become more assertive about new product value propositions. The US presidential election process will highlight payer complexities of the US healthcare system and continue to rattle investors.
- Payer recalcitrance continues to impair the pace of new product launches such as the PCSK9 antibodies Praluent and Repatha for hypercholesterolemia. Future launches will face similar pushback on price and volume.
- Investor's fund flows were negative in January and February 2016 but have begun to stabilize in recent months. Large asset managers reduced biotechnology holdings in the second half of 2015 and in 2016, but overall pressure diminished in the second, compared to the arduous first quarter 2016.
- Positive biotech pipeline news was only recently reflected in equity gains. This is encouraging compared to the first quarter 2016, when good news hardly moved the needle.

It was therefore appropriate that BB Biotech's strategy meeting in June included an expert panel on global drug pricing and reimbursement trends. Encouragingly, genuine innovation is anticipated to command premium pricing as long as innovators address market price realities. Experts believe that innovation continues as the strongest foundation for attractive prices. Health economic arguments are also gaining in importance and can help solve the equation of payer profitability – which remains their first priority. BB Biotech continues to monitor the political and legal landscape for healthcare reforms and changes but expects incremental rather than dramatic change particularly in the US.

Strong progress by many of the portfolio holdings was evident once more. At several companies this progress was not adequately reflected in equity valuations. Conversely, two negative news events were associated with

sharp share price reactions. However, BB Biotech believes the share price corrections of Ionis and Agios in connection with clinical news were overreactions. Furthermore, new investment candidates were identified in the small- and mid-cap category with attractive investment cases and which have the potential to develop into highly valued biotech companies in the future.

**BB Biotech Q2 2016 and H1 2016 performance**

For the second quarter 2016, BB Biotech's share return was -2.7% in CHF and -1.2% in EUR while the NAV gained +1.4% in CHF and +2.3% in EUR. The resulting gain for Q2 2016 was to CHF 36 mn.

For the first six months of 2016, BB Biotech's total share return was -18.8% in CHF and -18.4% in EUR. The total return for the NAV for the same period was -29.1% in CHF and -28.9% in EUR, corresponding to a net loss of CHF 1,170 mn.

BB Biotech investment leverage remained in double digits with an investment grade of 112.3% by end of June 2016. The year 2016 began with the fund 103.5% invested, by March 31 it was 112.8%.

**BB Biotech's portfolio continued to deliver milestones**

Net asset value began to stabilize – outperforming the biotech industry benchmark in the second quarter – while still slightly behind that benchmark year-to-date. Clinical trial results, product approvals, launches and one M&A announcement contributed to positive results in the second quarter. The NAV was pushed back by news of unexpected adverse events reported for two of Ionis' late-stage pipeline assets and also by Infinity's Pi3k inhibitor Duvelisib data which investors rated as underwhelming.

Other company news items were reported. Gilead received multiple product approvals for products in its leading HIV and HCV franchises. Both the US FDA and the European Agency EMEA approved the fixed-dose combination product Descovy (Emtricitabine, TAF) for treating HIV patients in April 2016. Gilead's HIV franchise was further strengthened with the positive CHMP opinion for Odefsey (Emtricitabine, Rilpivirine, TAF). Gilead also received US approval for Epclusa (Sofosbuvir, Velpatasvir) and a positive CHMP opinion for Epclusa. Despite these significant successes, Gilead's share price declined further in the second quarter as Q1 2016 financial results were below market expectations and investors continued to fret about the trajectory and longevity of the company's HCV business.

Actelion was granted European marketing authorization for Upravi to treat PAH patients in the second quarter. We believe this further strengthens the company. Intercept was granted accelerated approval for Ocaliva (obeticholic acid) for the treatment of patients with PBC (primary biliary cirrhosis) by the FDA. Swedish Orphan Biovitrum was granted EU approval for Alprolix, a recombinant Factor IX-Fc for the treatment of hemophilia B. In contrast to these positive regulatory events, Clovis terminated development of Rociletinib in lung cancer after receiving a complete response letter from the FDA.

Both Radius and Cempra made progress with lead assets. Radius submitted a new drug application (NDA) for Abaloparatide-SC for the treatment of postmenopausal women with osteoporosis. The submission was accepted for filing by the FDA and an approval decision is expected in early 2017. Also during the second quarter, Cempra submitted its NDA for Solithromycin for the treatment of community-acquired bacterial pneumonia in the US and Europe.

Late-stage clinical trial results lifted market sentiment during the second quarter. Tesaro doubled in market valuation after announcing strong Phase III data for Niraparib – a new class of anticancer drugs called PARP inhibitors in specific types of ovarian cancer. The trial met its primary endpoint of improved progression-free survival in the germline BRCA mutant cohort and in the non-germline BRCA mutant cohort, including both the HRD-positive and overall analysis populations. Tesaro plans to submit regulatory applications in the US and Europe later in 2016.

Regeneron and its partner Sanofi announced positive Dupilumab data in patients with inadequately controlled moderate-to-severe atopic dermatitis.

Alexion did not reach statistical significance for the primary efficacy endpoint with Soliris in patients with refractory generalized myasthenia gravis (gMG). Alexion's share price fell as investors registered concerns over long-term growth of Soliris.

Infinity announced results for its Pi3K inhibitor Duvelisib in patients with refractory indolent non-Hodgkin lymphoma. An overall response rate of 46%, all partial responders, is not considered competitive compared to other treatment options. Abbvie consequently returned worldwide marketing rights for Duvelisib.

Unexpected safety findings for Ionis' two late-stage pipeline candidates IONIS-TTRx and Volanesorsen resulted in a sharp decline in the company's valuation. While time will tell, BB Biotech regarded this as an overreaction by a sensitive biotech market.

Agios presented promising early-stage data for AG-348 in PK deficient patients.

Acquisition news played a minor role for BB Biotech's portfolio. Although large pharma and biotechnology companies emphasized their appetite for acquisitions at current low prices, none has yet landed a transaction. Sanofi offered USD 52 per share for Medivation in late April 2016. The company and the market was not impressed, but this story is anticipated to play out – Medivation has traded around USD 60 per share since the hostile take-over offer – and recently another buyer made a potentially better offer. BB Biotech will follow the situation closely.

### **Portfolio changes**

Careful adjustments were made to the portfolio during the second quarter of 2016. Infinity and Clovis were sold off. Three new small and midsized companies were added to the portfolio.

- Intra-Cellular Therapies is developing the lead molecule ITI-007 for the treatment of schizophrenia, bipolar disorder and behavioral disturbances in dementia. ITI-007 is an improved 5-HT<sub>2A</sub> serotonin receptor antagonist, designed to offer similar efficacy but improved tolerability profile compared to established drugs of the same class. The company has announced one positive Phase 3 study for schizophrenia, and a second Phase III trial is expected to readout in the third quarter of 2016.
- Macrogenics is an antibody technology company developing effector function improved antibodies and a novel platform called DART (Dual-Affinity-Re-Targeting) which offers potential for the efficient development of bispecific antibodies. This platform has been partially validated through multiple partnerships with major pharma companies.
- Tobira Therapeutics is developing Cenicriviroc, a dual CCR2 and CCR5 antagonist for treating patients with nonalcoholic steatohepatitis or NASH – a common, often "silent" liver disease. The company has a large Phase II study ongoing with data readout expected later in 2016.

### **Outlook for the sector and the portfolio**

BB Biotech anticipates further volatility of biotechnology equities in 2016. Nevertheless, product approvals and readouts from key clinical trials offer the potential for significant growth in valuations for the rest of 2016 and into 2017. Important regulatory and clinical trial milestones anticipated for companies in BB Biotech's portfolio include:

- Neurocrine – Valbenazine for patients with tardive dyskinesia
- Radius – Abaloparatide-SC for postmenopausal women with osteoporosis
- Medivation – label expansion for Xtandi for treating pre-chemo prostate cancer-patients

In addition, important clinical trial results are expected, including:

- Vertex – VX/661/Ivacaftor combination for treating cystic fibrosis patients that are heterozygous for the F508 deletion
- Incyte – Epcadostat in multiple Phase II studies in combination with various PD1 and PDL1 antibodies
- Celgene – Revlimid tested in the REMARC study for patients with diffuse large B-cell lymphoma
- Novavax – RSV vaccine Phase III study for the elderly
- Intra-Cellular – ITI-007 Phase III study for schizophrenia patients
- Tobira – Cenicriviroc Phase II for NASH patients

- Sage – SAGE-547 with a Phase III study for superrefractory status epilepticus in Q4 2016 and a Phase II study for postpartum depression in Q3 2016

These and other milestones are anticipated to support the strong fundamentals of BB Biotech's portfolio specifically and the biotechnology sector in general. With one of the weakest half year results now behind it, BB Biotech expects a return to growth from its portfolio holdings in the coming quarters and for FY 2016 as a whole. With many large pharmaceutical and biotechnology companies declaring interest in M&A, industry consolidation and opportunities for attractive exit prices could increase. However, BB Biotech's strategy remains focused on biotech companies offering innovation which promises to expand treatment options for important human diseases and to improve health outcomes significantly.

The complete interim report as of June 30, 2016 is available on [www.bbbiotech.com](http://www.bbbiotech.com)

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##### **Company profile**

BB Biotech invests in companies in the fast growing market of biotechnology and is one of the world's largest investors in this sector. BB Biotech is listed in Switzerland, Germany and Italy. Its investments are focused on listed companies that are developing and commercializing novel medical treatments and cures. BB Biotech's investment selection process is guided by the fundamental research and analysis of physicians and molecular biologists. Its Board of Directors has many years of experience in industry and science.

##### **Disclaimer**

This release contains forward-looking statements and expectations as well as assessments, beliefs and assumptions. Such statements are based on the current expectations of BB Biotech, its directors and officers, and are, therefore, subject to risks and uncertainties that may change over time. As actual developments may significantly differ, BB Biotech and its directors and officers accept no responsibility in that regard. All forward-looking statements included in this release are made only as of the date of this release and BB Biotech and its directors and officers assume no obligation to update any forward-looking statements as a result of new information, future events or other factors.

## Composition of BB Biotech's portfolio as of June 30, 2016

(in % of securities, rounded values)

Celgene	11.8%
Incyte	10.2%
Actelion	9.3%
Gilead	7.7%
Ionis Pharmaceuticals	5.5%
Radius Health	5.3%
Neurocrine Biosciences	4.7%
Alexion Pharmaceuticals	4.6%
Vertex Pharmaceuticals	4.0%
Novo Nordisk	4.0%
Medivation	4.0%
Agios Pharmaceuticals	3.3%
Tesaro	3.2%
Regeneron Pharmaceuticals	2.4%
Alnylam Pharmaceuticals	2.2%
Halozyme Therapeutics	2.1%
Novavax	2.0%
Swedish Orphan Biovitrum	1.8%
Juno Therapeutics	1.7%
Alder Biopharmaceuticals	1.4%
Kite Pharma	1.2%
Intercept Pharmaceuticals	1.2%
Cempra	1.1%
Intra-Cellular Therapies	0.9%
Sage Therapeutics	0.8%
Probiodrug	0.7%
Macrogenics	0.5%
Puma Biotechnology	0.4%
Prothena Corp.	0.4%
Achillion Pharmaceuticals	0.3%
Esperion Therapeutics	0.3%
PTC Therapeutics	0.3%
Cidara Therapeutics	0.3%
Tobira Therapeutics	0.2%
Radius Health warrants 04/23/2018	0.1%
Radius Health warrants 02/19/2019	0.1%
Merck & Co Inc Contingent Value Rights – ex Trius/Cubist	0.0%
<b>Total securities</b>	<b>CHF 2 945.0 mn</b>
Other assets	CHF 32.8 mn
Other payables	CHF (356.5) mn
<b>Total shareholders' equity</b>	<b>CHF 2 621.3 mn</b>
Treasury shares (in % of company) <sup>1)</sup>	7.0%

1) Corresponds to the total of all own shares held including the second trading line

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Numero di Pagine: 7